

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-1458V

Filed: May 6, 2019

UNPUBLISHED

DENISE GORING,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Special Processing Unit (SPU);
Ruling on Entitlement; Decision after
Fact Hearing and Ruling; Causation-
In-Fact; Tetanus Diphtheria acellular
Pertussis (Tdap) Vaccine; Additional
Non-covered Vaccine; Alternative
Causation Burden of Proof; Shoulder
Injury Related to Vaccine
Administration (SIRVA)

Isaiah Richard Kalinowski, Maglio Christopher & Toale, PA, Washington, DC, for petitioner.

Voris Edward Johnson, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT¹

Dorsey, Chief Special Master:

On November 4, 2016, Denise Goring (“petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*,² (the “Vaccine Act”). Petitioner alleges that she suffered left shoulder injuries caused by vaccinations she received on October 19, 2015. Petition at

¹ The undersigned intends to post this ruling on the United States Court of Federal Claims' website. **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access. Because this unpublished ruling contains a reasoned explanation for the action in this case, undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services).

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

1-2. Petitioner received two vaccines, one covered and one non-covered, in the arm where she suffered an injury.

The parties dispute whether this case may be analyzed as a Table case or petitioner must establish causation-in-fact; whether petitioner has established that a covered vaccine caused her injury; and who has the burden of proof as to whether factors unrelated to the covered vaccine caused her injury and whether this has been established in this case. For the reasons stated herein, the undersigned finds that, whether analyzed as a Table case or causation-in-fact case, the petitioner has established a prima facie case that she suffered a shoulder injury caused by a covered vaccine. The undersigned further determines that respondent has the burden of proof to show that unrelated factors caused petitioner's injury and that he has not met this burden.

I. Procedural History

On November 4, 2016, Ms. Goring filed her petition (ECF No. 1). On the same day, she filed medical records marked as Exhibits 1-6 (ECF No. 4). The case was assigned to the Special Processing Unit of the Office of Special Masters. She filed additional medical records, Exhibit 7, and a Statement of Completion on November 28, 2016 (ECF Nos. 9 and 10). The initial status conference was held on January 10, 2017 and respondent was directed to file a status report concerning the completeness of the records and how respondent intended to proceed in this case (ECF No. 11).

On February 3, 2017, petitioner filed an additional medical record marked as Exhibit 8 and an affidavit designated Exhibit 9 (ECF No. 12). On February 24, 2017, respondent filed a status report identifying missing records needed to determine respondent's position in this case (ECF No. 13). On the same day, petitioner filed a status report in response concerning the medical records identified by respondent and stating that petitioner sent a demand letter to respondent on February 24, 2017 (ECF No. 14).

On February 27, 2017, the undersigned issued a scheduling order directing respondent to file a status report proposing appropriate next steps (ECF No.15). From March to June 2017 the parties engaged in discussions attempting to informally resolve this matter (ECF Nos. 16-23). On July 20, 2017, petitioner filed a status report informing the court that the parties had been unable to resolve the matter informally and proposing that the court schedule a deadline for the filing of respondent's Rule 4(c) Report (ECF No. 25). On July 21, 2017, petitioner filed additional medical records as Exhibit 10 (ECF No. 28).

On August 10, 2017, respondent filed a Rule 4(c) Report (ECF No. 29) asserting that petitioner had not established entitlement to compensation. The court scheduled a status conference for August 28, 2017 to discuss with the parties how to proceed. Before the status conference took place, on August 28, 2017, petitioner filed a motion for summary judgment (ECF No. 30). The August 28, 2017 status conference was

cancelled. Respondent filed a response to the summary judgment motion (ECF No. 31), and petitioner filed a reply (ECF No. 32). Petitioner filed an additional affidavit on September 20, 2017 (ECF No. 33).

On October 4, 2017, the undersigned denied the summary judgment motion (ECF No. 34) and directed petitioner to file additional affidavits, medical records, and an expert report (ECF No. 35). On December 13, 2017, petitioner filed additional medical records, a detailed affidavit, and medical literature (ECF Nos. 39 and 40). Also on December 13, 2017, petitioner filed a status report and request for a status conference (ECF No. 41).

On January 23, 2018, the undersigned held a status conference with counsel for both parties. On January 24, 2018, petitioner filed a status report confirming that she sent a detailed counter-offer to respondent (ECF No. 44). On February 1, 2018, the undersigned issued an order directing petitioner to obtain an expert report addressing a lipoma on petitioner's back as an alternative cause of her shoulder condition. Scheduling Order, issued Feb. 1, 2018 (ECF No. 45). In the February 1, 2018 order, the undersigned further stated that absent additional evidence, the undersigned was inclined to rule that respondent had not met his burden of proving alternative causation. *Id.*

On April 24, 2018, petitioner filed medical records from Dr. Ellis Nam of Chicago Orthopaedics & Sports Medicine, S.C. (ECF No. 50-2). On May 30, 2018, petitioner filed a May 18, 2018 addendum to Dr. Nam's earlier records (ECF No. 53-2). On May 30, 2018, the parties and OSM staff attorney held a status conference to discuss how to proceed. On June 1, 2018, the undersigned issued an order determining that the case should proceed to a hearing to resolve the onset of petitioner's symptoms, the site of administration of petitioner's vaccinations, and whether a lipoma on petitioner's back was a condition or abnormality that would explain her symptoms (ECF No. 54). A fact hearing was thereafter scheduled for September 18, 2018.

On September 18, 2018, a fact hearing was held in Washington, D.C. Transcript of Hearing held on September 18, 2019 ("Tr.") (ECF No. 63). Ms. Goring was the sole witness and she appeared in person with her attorney. At the conclusion of the hearing, the undersigned issued a ruling from the bench. On the same day, the undersigned issued a scheduling order directing the parties to consult and determine whether, in light of the resolution of the disputed factual issues, they were able to resolve this matter through negotiations. Scheduling Order, issued Sept. 18, 2018 (ECF No. 60). On October 3, 2018, the parties filed a joint status report stating that they had attempted in good faith to resolve this matter but were unable to do so. Joint Status Report, filed Oct. 3, 2018 (ECF No. 61).

On October 31, 2018, the undersigned issued a fact ruling memorializing the bench ruling. Fact Ruling, 2018 WL 6539219 (Fed. Cl. Spec. Mstr. Oct. 31, 2018) (ECF No. 65). The undersigned first determined that petitioner's Tetanus Diphtheria acellular

Pertussis (“Tdap”) and shingles vaccines were administered in her left arm. *Id.* at *3. Next, the undersigned determined that the onset of petitioner’s left shoulder injuries occurred within 48 hours of her October 19, 2015 vaccinations. *Id.* at *4.³ Finally, the undersigned determined that a lipoma on petitioner’s back was incidental and not a condition or abnormality that explained her symptoms. *Id.*

On October 31, 2018, the undersigned issued a scheduling order filing as court exhibits two articles pertaining to causation of vaccine-related shoulder injuries. Scheduling Order, issued Oct. 31, 2018 (ECF No. 64). These articles are: S. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010), filed as Court Exhibit I, and M. Bodor and E. Montalvo, *Vaccination Related Shoulder Dysfunction*, 25 Vaccine 585 (2007), filed as Court Exhibit II (ECF No. 64).

In the October 31, 2018 scheduling order, the parties were given until December 7, 2018 to provide additional evidence concerning entitlement or any response to the court exhibits, and to file memoranda addressing the implications of petitioner’s receipt of a vaccine covered by the Vaccine Program as well as a non-covered vaccine in her injured arm. *Id.* After that time, the parties were informed, the record concerning entitlement would close and the undersigned intended to issue a decision or ruling concerning entitlement. *Id.*

In addition, the undersigned informed the parties that as previously indicated in a February 1, 2018 scheduling order (ECF No. 45), the undersigned was inclined to rule in this case that respondent had the burden of proving alternative causation and had not met that burden. Scheduling Order, issued Oct. 31, 2018 (ECF No. 64).

The undersigned cited the decision of the United States Court of Appeals for the Federal Circuit in *Walther v. Sec’y of Health and Human Servs.*, 485 F. 3d 1146 (Fed. Cir. 2007), as establishing that once petitioner has established a prima facie case, the government bears the burden of establishing alternative causation by a preponderance of the evidence. *Id.* The undersigned noted that she had previously applied the reasoning set forth in *Walther* to find, in a case where a petitioner received both a covered and non-covered vaccine in the injured arm, that the government bears the burden of establishing that the non-covered vaccine caused the injury.⁴ *Id.* The undersigned informed the parties that absent additional evidence, she was inclined to rule in this case that petitioner had established a prima facie case and respondent had

³ The October 31, 2018 fact ruling contained a typographical error in the conclusion, stating that onset of petitioner’s *right* shoulder injuries was within 48 hours of vaccination. *Id.* at *4. As the remainder of the fact ruling makes clear, petitioner’s injuries were to her *left*, not right, shoulder.

⁴ The previous decision involving this issue is *Zebofsky v. Sec’y of Health & Human Servs.*, No. 15-1084V, 2017 WL 7051381 (Fed. Cl. Spec. Mstr. Sept. 28, 2017) (applying *Walther* and determining that respondent had not provided evidence to establish an alternative cause of petitioner’s injury in a case also involving two vaccines, one covered and one non-covered, in the same arm). No motion for review was filed following the decision.

not met his burden of proving that the non-covered vaccine, rather than the covered vaccine, caused petitioner's injury. *Id.*

Finally, in the October 31, 2018 scheduling order, the undersigned noted that respondent had, in his Rule 4(c) Report, appeared to argue that petitioner alleged that a flu vaccine in her right shoulder had caused a SIRVA in her left shoulder.⁵ *Id.* The undersigned noted that in a February 1, 2018 scheduling order (ECF No. 45), the undersigned indicated that while the petition may have been ambiguous as to which vaccine was alleged to have caused petitioner's injury, it appeared that the claim was based on the Tdap vaccine. *Id.* The undersigned invited the parties to file additional evidence on this matter as well. *Id.*

On December 4, 2018, petitioner filed a motion for summary judgment (ECF No. 66). On December 7, 2018, respondent filed a response to the court's October 31, 2018 scheduling order (ECF No. 67). On December 13, 2018, respondent filed a response to petitioner's December 4 summary judgment motion (ECF No. 69). On December 20, 2018, petitioner filed a reply (ECF No. 70). This case is now ripe for a decision on petitioner's second summary judgment motion and a ruling on entitlement.

II. Factual History

Denise Goring was 60 years old when she received influenza, Tetanus Diphtheria acellular Pertussis ("Tdap"), and shingles vaccines at a Department of Defense installation in Texas on October 19, 2015. Petitioner's Exhibit ("Pet. Ex.") 1 at 1; Pet. Ex. 11 at 1; Pet. Ex. 15 at 1. The Vaccine Administration Record filed as Pet. Ex. 1 lists all three of these vaccines as having been given on that date, and lists the manufacturer and lot number, but does not list the vaccination sites. Pet. Ex. 1.

Petitioner asserts in her detailed fact affidavit that the influenza vaccination was administered in her right arm, while the Tdap and shingles vaccinations were administered in her left arm. Pet. Ex. 15 at ¶ 2. She states that she remembers which vaccinations were administered into which arm because of the circumstances of their administration. Pet. Ex. 15 at ¶ 3. Specifically, she states that she went to the clinic that day only to receive a flu shot, which the technician injected into her right shoulder first. *Id.* However, after administering the flu shot, the technician inquired how long it had been since petitioner had a tetanus booster. *Id.* at ¶ 4.

Petitioner asserts that the technician convinced her to have a tetanus, or Tdap, shot, which she administered into petitioner's upper left arm since she had already administered a flu shot into petitioner's right shoulder. *Id.* As petitioner and the

⁵ Respondent's argument is somewhat difficult to follow but appears to be that because petitioner's initial affidavit mentioned only the arm of vaccination of her flu shot, which was administered into her right arm, that meant that petitioner was alleging that a flu shot in her right arm caused a SIRVA in her left shoulder. To the extent that this is respondent's interpretation, the undersigned does not agree with respondent that petitioner asserts a flu shot in her right arm caused a SIRVA in her left shoulder.

technician continued to talk, the technician persuaded her to get a shingles vaccination as well, which was administered into petitioner's left arm. *Id.* at ¶ 5. Petitioner states that because of these circumstances, she is confident that she accurately recalls which vaccinations were administered into which arm. *Id.* at ¶ 6. On October 19, 2015, petitioner also presented to Dr. Judy Rattan in the optometry clinic at Randolph Air Force Base for an eye exam. Pet. Ex. 4 at 209.

Prior to the October 19, 2015 vaccinations, petitioner had no prior history of shoulder pain or shoulder injury. See generally Pet. Ex. 3, Pet. Ex. 4, Pet. Ex. 7. Petitioner states in her detailed affidavit that she began to experience "distinct pain and inflammation swelling almost immediately" after the vaccines were administered. Pet. Ex. 15 at ¶ 7. Petitioner testified that at the moment of injection, she "didn't feel anything on my right side where my flu shot was . . . I felt like a tingling on my left side [after the administration of] both the tetanus and the shingles [vaccines]." Tr. 10-11. She testified that she began to experience soreness in her left shoulder "immediately pretty much after she administered those two [tetanus and shingles vaccines] in my left arm . . . what kind of startled me, I noticed that it was kind of inflamed." Tr. 11.

Petitioner states that the pain began before she left the clinic, that she inquired about it and was told it was normal and would go away. Pet. Ex. 15 at ¶ 7. Petitioner states that the area surrounding the injection site on her upper left arm was noticeably swollen by the time she returned to the place where she was staying in Texas.⁶ *Id.*

Petitioner's detailed affidavit states that the day following the vaccine "the pain [in her left arm] became so bad, I knew there was a problem." *Id.* at ¶ 8. Petitioner states that she telephoned the clinic and was again assured that the pain was normal and would go away. *Id.* Petitioner states that by the second day after vaccination, the pain remained and she also had difficulty with movement in her left arm. *Id.* at ¶ 9. Petitioner states that she again called the clinic and was told not to worry and that the pain could be expected to continue for the next two weeks before going away. *Id.*

In her detailed affidavit, petitioner states that by one week following vaccination, she "could not move my left arm nearly at all, and it was basically incapacitated from that point onward." *Id.* at ¶ 10. She states that she "could barely lift my arm to comb my hair, and could hardly use my left hand at all." *Id.* After two weeks passed and she was still in pain, she called the facility again but "they again dismissed my concerns, stating that sometimes it can take even longer for the pain to go away." *Id.* at ¶ 11. She states that she "could see that the staff at the clinic were not taking this injury seriously [and] decided I needed to set up an appointment with my doctor in Chicago for when I returned there from Texas." *Id.*

⁶ At the hearing, petitioner explained that she lives in Chicago but visits San Antonio twice a year to visit her grown children and that while she is there she sees her dentist and medical providers. Tr. 55.

Petitioner asserts that she does not have records from October or November documenting her injury because her concerns were not taken seriously initially and because she was unable to obtain an appointment when she sought evaluation and treatment. Pet. Ex. 15 at ¶ 21. In her detailed affidavit, petitioner states that she called her primary care physician in Chicago seeking an appointment before the end of November, but the soonest she could obtain an appointment was in late December. Pet. Ex. 15 at ¶ 12. Petitioner states that she was finally able to see Dr. Karen Noriega on December 22, 2015. *Id.* at ¶ 13.

On December 22, 2015, petitioner presented to Dr. Karen Noriega at Mercy Hospital and Medical with a chief complaint of “LT [left] ARM PAIN AFTER 2 SHOTS x 2 MONTHS; GETTING WORST.” Pet. Ex. 3 at 42. In the same paragraph, the visit notes state that she complained of “left arm pain after shingles vaccination 10/2015 in texas military base, pt [patient] feels pain is worsening where she cannot lift her left arm over her head.” *Id.* While the medical record reflects that petitioner attributed her pain to her shingles vaccination, petitioner testified that she “mentioned all three” vaccines that she had received. Tr. 21.

On examination, her left arm was found to have decreased range of motion and tenderness to deep palpation. *Id.* at 45. She could not lift her left arm above her head and her left arm was weaker than her right arm. *Id.* Dr. Noriega ordered a CT scan of petitioner’s left shoulder. *Id.* Petitioner states that Dr. Noriega prescribed pain medication and referred her for an MRI; however, her insurance declined coverage for the MRI because she had not first had an x-ray. Pet. Ex. 15 at ¶ 14.

On January 19, 2016, petitioner presented to the emergency room at Mercy Hospital and Medical Center with a chief complaint of left arm pain. Pet. Ex. 3 at 278. She complained of left shoulder pain “ongoing since 10/2015, states she first felt pain after she received vaccine for shingles. Since then has had significant pain and has experienced limited range of motion of LUE [left upper extremity, or arm] and shoulder. *Id.* at 298. On examination, she was found to have mild tenderness to palpation and limited range of motion in her left shoulder. *Id.* She was given shoulder x-rays, which did not identify any fracture or dislocation. *Id.* at 294. She was also given a chest CT, which noted a fat density mass “which likely represents a lipoma.” *Id.* at 296.

The examining physician found that the pain was reproducible with range of motion of the left shoulder. She was diagnosed with left shoulder pain not otherwise specified, left posterior chest wall lipoma, and possible adrenal lipoma. The [doctor] noted that the pain was “chronic in nature since 10/2015 limiting movement” and determined that the shoulder pain was “likely related to rotator cuff pathology, possibly related to large lipoma.” Pet. Ex. 3 at 298. Petitioner was discharged and directed to follow up with her primary care physician. *Id.*

Petitioner states that the “lipoma was on my back and side, essentially, below my shoulder and scapula . . . not near my shoulder.” *Id.* Petitioner asserts that the lipoma

“has been present on my back for about 15 years, and has never caused me adverse symptoms or concern.” Pet. Ex. 15 at ¶ 18. In her detailed affidavit, executed on December 11, 2017, petitioner asserts that “[t]o this day, the Lipoma is still on my back.” Pet. Ex. 15 at ¶ 20. She asserts that as her injury developed and later improved, the lipoma has remained there. *Id.*

On January 26, 2016 petitioner presented to Dr. Kimberly Townsend-Scott. Pet. Ex. 3 at 326. At this visit, she complained of left shoulder pain that she reported began after receiving two immunizations in her left arm. *Id.* Petitioner reported having been seen in the emergency room for this and directed to follow up with her doctor, but reported she was unable to get an appointment with her primary doctor, Dr. Dhir, until March 2016. *Id.* She was diagnosed with left arm pain, lipoma, adrenal mass, and hypertension. *Id.* at 331. Dr. Townsend-Scott referred her to surgery for evaluation and possible excision of the lipoma. *Id.* at 332. For her shoulder pain, Dr. Townsend-Smith discussed physical therapy if excision of the lipoma did not provide relief. *Id.*

On February 2, 2016, petitioner was seen by Dr. Nicholas Leroy at the Center for Progressive Health. Pet. Ex. 2 at 3-4; Tr. 74. The visit notes reflect that petitioner was seen for left shoulder pain following tetanus and shingles shots in her left deltoid in October. Pet. Ex. 2 at 4. Petitioner reported that she could not raise her left arm above horizontal. She reported fever and night sweats since the vaccinations. *Id.* On examination, she was found to be severely restricted in internal and external rotation in her left shoulder. She was found to have tenderness in her left deltoid muscle, left subscapularis muscle, and left infraspinatus muscle. *Id.* Dr. Leroy assessed petitioner as having left “rot. [rotator] cuff syndrome 2° [secondary] to Oct 2015 vaccine shots [in left] deltoid.” *Id.* at 3. Myofascial release for rotator cuff or physical therapy was recommended. *Id.*

On February 18, 2016, petitioner presented to Dr. Andrew Perrott. Pet. Ex. 14 at 3. She reported that she had injections in her left deltoid in October and since then had pain in her left shoulder region, particularly with certain movements. *Id.* She had a deep-seated lipoma of the left chest wall, but it was not tender. *Id.*

On physical examination, petitioner was found to have restriction in left shoulder movement with abduction of about 60 degrees and extension of 90 degrees. *Id.* at 4. Dr. Perrott diagnosed petitioner with an “incidental lipoma” and noted that petitioner “agrees that excision of this [is] unlikely to change [her] shoulder problem.” *Id.* He added, “Shoulder ? rotator cuff syndrome as cause of her discomfort.” *Id.* Dr. Perrott discussed referral to an orthopedist or physical therapy and petitioner stated that she would like to try physical therapy first. *Id.* Dr. Perrott ordered physical therapy consultation and treatment. *Id.* at 7.

On March 28, 2016, petitioner underwent an initial physical therapy evaluation for her left shoulder pain. Pet. Ex. 5 at 54. She reported that in the end of October 2015 she had tetanus and shingles vaccines in her left arm and after two weeks the pain in

her left shoulder increased. *Id.* She reported noticing tissue changes in her left shoulder following the shot and having pain. *Id.* She initially had pain at rest in her left shoulder, but at the time of evaluation she experienced pain only with movement. *Id.* at 56. She reported limited range of motion when putting her arm behind her back and reaching over her head. *Id.* On examination, she was found to have limited and painful range of motion and reduced strength in her left shoulder. *Id.* at 55. She had tenderness to palpation over the insertion of her left deltoid and her upper trapezius muscle and positive signs on Hawkins and Kennedy impingement tests. *Id.*

On April 18, 2016, petitioner presented to Universal City Family Practice in Universal City, TX, to follow up on labs. Pet. Ex. 7 at 3. The visit notes are handwritten and difficult to read. There appears to be a mention of her left shoulder problem, but the notes are unclear as to what was discussed or recommended. *Id.* at 4.

On November 7, 2016, petitioner was seen by Dr. Kokebie for a rheumatology consultation with a chief complaint of right wrist and right knee pain. Pet. Ex. 10 at 1. Petitioner reported that her right knee pain started in August after a car accident. *Id.* Petitioner reported that the right wrist pain “started 2 months ago since she was favoring her right arm due to tetanus and zoster vaccines in the left shoulder [which] was [very] painful.” *Id.*

On March 8, 2018, petitioner presented to Dr. Ellis Nam of Chicago Orthopaedics and Sports Medicine, S.C. for examination. Pet. Ex. 23 at 3. She reported left shoulder pain that began “2 years ago, October 2015, after she had a tetanus/shingles shot in her left shoulder. No prior problems left shoulder prior to the injection.” *Id.*

Dr. Nam assessed petitioner as having left shoulder pain following tetanus and shingles vaccinations in October 2015, with “possible [rotator] cuff tear.” *Id.* at 4. He recommended an MRI of the left shoulder to rule out a rotator cuff tear, but noted that petitioner did not want a left shoulder MRI. *Id.* Dr. Nam noted that petitioner inquired whether a lipoma on her back resulted in her shoulder condition. He stated, “I believe her lipoma seen in her ct scan of her left upper back was unrelated to her left shoulder condition she developed after her vaccination.” *Id.*

On May 18, 2018, Dr. Nam added an addendum to petitioner’s medical records. Pet. Ex. 24. On May 30, 2018, petitioner filed Exhibit 24 and Exhibit 25, the curriculum vitae of Ellis Kevin Nam, M.D. Exhibit 25 was labeled in CM/ECF as “Expert CV” (ECF No. 53). In Exhibit 24, Dr. Nam stated:

Patient has an incidental lipoma on her back which was unrelated to her left shoulder condition she developed as a result of the tetanus/shingles shot in her left shoulder on October, 2015. The lipoma’s location is on her back and NOT on her left shoulder. They are in separate distinct anatomic locations in her body. As a result, the lipoma has no relationship to her left shoulder and has no influence in [petitioner] developing left shoulder pain after her injection she received on October, 2015.

Pet. Ex. 24 at 1.

III. Parties' Arguments

a. Petitioner's Arguments

In her summary judgment motion filed on December 4, 2018 ("Petitioner's Second MSJ") (ECF No. 66-1), petitioner asserts that she has satisfied the requirements of § 13 of the Vaccine Act by establishing the factual matters set forth in § 11(c)(1). Specifically, petitioner asserts that she has shown that she received the Tdap vaccine, which is set forth in the Table; received the vaccine in the United States; sustained a SIRVA as described in the QAI within the time set forth in the Table; suffered the residual effects of her injury for more than six months after vaccination; and has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury.

Petitioner asserts that respondent has not met the burden required by § 13(a)(1)(B) to rebut petitioner's proof establishing entitlement because respondent has not filed any evidence to meet this burden. Petitioner asserts that she has established that the Table criteria for SIRVA are met. In short, petitioner argues that respondent bears the burden of proof of demonstrating the shoulder injury was caused by the shingles vaccination rather than the Tdap vaccination, and that respondent has not met this burden.

b. Respondent's Arguments

Respondent argues that because the petition in this case was filed prior to SIRVA being added to the Table, petitioner is not entitled to a presumption of causation and must prove that the vaccine actually caused her SIRVA. Respondent's December 7, 2018 Brief in Response to October 31, 2018 Scheduling Order ("Respondent's December 7, 2018 Brief"), filed Dec. 7, 2018, at *2 (ECF No. 67). Respondent asserts that petitioner must establish by preponderant evidence that the Tdap vaccination, rather than the shingles vaccine, was the cause of her SIRVA. *Id.* at 2-3. Respondent asserts that "there is no evidentiary basis for [the undersigned] to conclude that the Tdap vaccine was more likely than the shingles vaccine to have caused petitioner's SIRVA, and indeed any such finding to that effect would constitute legal error." *Id.* at 3. Respondent acknowledges that petitioner could re-file her petition to allege a Table SIRVA claim but asserts that because she has not done so, "her claim therefore must be analyzed under the legal standards in effect on the date her petition was filed." *Id.*, at *2 n.2.

Respondent asserts that because the intramuscular administration of any vaccine could potentially cause a SIRVA, it is reasonable to infer in this case that the non-covered vaccination alone, in this case shingles, caused petitioner's SIRVA. Respondent's Opposition to Petitioner's Second Motion for Summary Judgment ("Respondent's Opposition to Second MSJ"), filed Dec. 13, 2018, at *2 (ECF No. 69).

Respondent cites *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986), for the proposition that, in evaluating a summary judgment motion, all justifiable inferences should be drawn in favor of the non-movant. *Id.* Respondent asserts that petitioner cannot show that the covered vaccination more likely than not caused her SIRVA and thus “there is a genuine dispute as to a material fact that precludes summary judgment for petitioner.” *Id.*

Respondent declined to submit evidence concerning entitlement. Respondent’s December 7, 2018 Brief at *1 n.1 (ECF No. 67) (“Respondent elects not to submit any additional evidence at this time, because he is not the burdened party and because, as explained herein, the record evidence currently fails to satisfy petitioner’s burden of proof as a matter of law”) (emphasis added).

IV. Summary Judgment Standards for Adjudication and Analysis

Pursuant to Vaccine Rule 8(d), a special master may decide a case based on a summary judgment motion. If a summary judgment motion is filed, Rule of the Court of Federal Claims (“RCFC”) 56(a) applies and allows the court to decide a claim on summary judgment “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”

“The party moving for summary judgment ‘bears the burden of demonstrating absence of all genuine issues of material fact.’” *Jay v. Sec’y of Health and Human Servs.*, 998 F.2d 979, 982 (Fed. Cir. 1993) (quoting *SRI Int’l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1116 (Fed.Cir.1985) (en banc)). If the evidence presented is insufficient to permit a reasonable factfinder to find in favor of the nonmoving party, there is no genuine issue of material fact. *Jay*, 998 F.2d at 982 (citing *Anderson*, 477 U.S. at 249). “The summary judgment inquiry in essence is whether the evidence presents a sufficient disagreement of fact to require submission to the factfinder or whether it is ‘so one-sided that one party must prevail as a matter of law.’” *Id.*

The existence of a dispute as to a legal issue does not preclude the entry of summary judgment. See *Howes v. Medical Components, Inc.*, 814 F.2d 638, 643 (Fed. Cir. 1987) (in patent case, stating that claim construction is a question of law and “the mere existence of a dispute as to that legal issue does not preclude summary judgment”).

In the October 31, 2018 fact ruling, the undersigned resolved several disputed factual issues, including the site of administration of petitioner’s October 19, 2015 vaccinations, the onset of her shoulder injury, and whether a lipoma on her back caused her shoulder symptoms.

Respondent appears to assert that whether a non-covered vaccination, shingles, caused petitioner’s injury is a disputed material fact that precludes summary judgment. However, respondent concedes that “the record evidence establishes, at best, that the Tdap vaccine and the shingles vaccine were both *equally likely* to have caused

petitioner's SIRVA." Respondent's December 7, 2018 Brief at *1-2 (ECF No. 67) (emphasis added).

Respondent has offered no proof to demonstrate that the non-covered shingles vaccine was more likely than the Tdap vaccine to have caused petitioner's SIRVA or that the Tdap vaccine did not cause petitioner's SIRVA. Thus, the evidence is insufficient to permit a reasonable factfinder to find in respondent's favor. Therefore, under the *Jay* standard, there is no genuine issue of material fact in this case and summary judgment is appropriate.

Moreover, with respect to the "fact" that respondent asserts is disputed, the undersigned has made all factual findings that can be made on this issue based on the evidence in the record, and the remaining issues pertain to the legal implications of the facts that have been found.

All that remains to be resolved concerning entitlement in this case are the following issues: whether petitioner's case may be analyzed as a *Table* case or petitioner must establish causation in fact; whether petitioner has established causation under the appropriate standard; and how to analyze the effect of a potential alternative cause and who bears the burden of proof on a potential alternative cause pursuant to § 13(a)(1)(B). There are no remaining issues of material fact. Thus, this case is appropriate for resolution on summary judgment.⁷

The court previously informed the parties that on December 7, 2018, "the record in this matter with regard to entitlement will close and a ruling or decision will issue thereafter." Scheduling Order, issued Oct. 31, 2018 (ECF No. 64). The parties have had ample opportunity to submit evidence and arguments on the issue of entitlement. The undersigned has fully considered the issues raised in Petitioner's Second MSJ [ECF Nos. 66, 66-1], Respondent's Opposition to Second MSJ [ECF No. 69], petitioner's reply ("Petitioner's Reply, Second MSJ") [ECF No. 70], and Respondent's December 7, 2018 Brief [ECF No. 67]. For the reasons described below, the undersigned finds that petitioner is entitled to compensation.

V. Legal Standard for Establishing Causation

In order to establish entitlement to compensation under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1). § 13(a)(1)(A). In determining whether a petitioner has done so, the special master or court should consider the record as a whole. § 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

⁷ Even if summary judgment were not appropriate, this is a case where a motion for a ruling on the record could have been filed and granted in petitioner's favor. See Vaccine Rule 8(d) (allowing a special master to decide a case on the basis of written submissions). The parties have fully briefed the disputed issues concerning entitlement in the summary judgment motion papers and respondent's December 7, 2018 brief. Thus, the undersigned determines that it is appropriate to determine entitlement.

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,⁸ a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. § 11(c)(1)(C). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a).

The injury alleged in this petition is a shoulder injury related to vaccine administration ("SIRVA"). Petition (ECF No. 1) at *1-3. SIRVA was added to the Vaccine Injury Table effective for petitions filed on or after March 21, 2017.

The petition in this case was filed on November 4, 2016, four months prior to the effective date of the amendments adding SIRVA to the Table. If the petition in this case had been filed on or after March 21, 2017, as it could have been under the lookback provision in § 16(b), the parties agree that the revised Table would be applicable. See, e.g., respondent's statement that "[r]espondent acknowledges that petitioner could dismiss the instant claim and re-file her petition to allege a Table SIRVA claim. However, she has not done so, and her claim therefore must be analyzed under the legal standards in effect on the date her petition was filed." Respondent's December 7, 2018 Brief at *2 n.2 (ECF No. 67).

Because this case was filed prior to the effective date of the Table amendments, the parties dispute whether it may be analyzed as a Table case. In August 2017, the parties debated this issue in their submissions for and against the first summary judgment motion. This issue was also contested in respondent's Rule 4(c) Report, Respondent's December 7, 2018 Brief, and the submissions for and against the second summary judgment motion filed in December 2018.

Both parties agree that pursuant to Vaccine Act § 14(c)(4), any Table modifications "shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation." See Petitioner's First Motion for Summary Judgment, filed Aug. 28, 2017 (ECF No. 30-1), at *8; Respondent's Response to First Motion for Summary Judgment, filed Aug. 30, 2017 (ECF No. 31), at *13. However, they differ in their view as to how respondent has implemented Table modifications in the past.

Petitioner argues that this case should be treated as a Table case. In the Summary Judgment Motion filed on August 28, 2017 (ECF No. 30), petitioner asserted that respondent had a long-standing policy of applying Table changes without reference

⁸ In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See § 11(c)(1)(A)(B)(D)(E).

to whether the petition was filed before or after the Table changes took effect. Petitioner's First Summary Judgment Motion, filed Aug. 28, 2017 (ECF No. 30-1). Petitioner argued that respondent has conceded many cases in recent years that would only have become Table injuries once the recent Table changes took effect in March 2017. *Id.* at *9-10.

In his response to the first summary judgment motion, respondent stated that "had respondent determined that the facts of this case met the Table criteria, respondent would have conceded entitlement to compensation." Response to First Motion for Summary Judgment, filed Aug. 30, 2017, at *14 (ECF No. 31). Yet in Respondent's December 7, 2018 Brief, respondent asserted that because this case was filed before the Table amendments took effect, "petitioner may not take advantage of the benefits of presumed causation afforded to Table injury claims." Respondent's December 7, 2018 Brief at *2 (ECF No. 67). Respondent acknowledges that "petitioner could dismiss the instant claim and re-file the petition to allege a Table SIRVA claim. However, she has not done so, and her claim therefore must be analyzed under the legal standards in effect on the date her petition was filed." *Id.* at n.2.

Thus, respondent appears to have taken inconsistent positions, having earlier stated that if this case met Table criteria respondent would have conceded the case, yet now asserting that this case cannot be treated as a Table case because petitioner did not dismiss this case and file a new petition.

While petitioner could have filed a new petition following the effective date of the Table amendments adding SIRVA to the Table,⁹ she did not. Petitioner's assertion that respondent's practice is to concede cases meeting Table criteria even if the petition was filed prior to the Table revision is supported by respondent's earlier assertion that "had respondent determined that the facts of this case met the Table criteria, respondent would have conceded entitlement to compensation." Respondent's Response to First Motion for Summary Judgment, filed Aug. 30, 2017, at *14 (ECF No. 31).

Nevertheless, the undersigned cannot ignore the clear language of § 14(c)(4) that Table modifications "shall apply only with respect to petitions for compensation" filed after the effective date of the Table revisions. Thus, the undersigned proceeds to analyze this case as if the March 21, 2017 revisions adding SIRVA to the Table do not expressly govern entitlement in this case.

The undersigned finds that whether this is analyzed as a Table case or a causation-in-fact case, petitioner has established a prima facie case and respondent has not established that a factor unrelated to the Tdap vaccine caused petitioner's SIRVA. For purposes of this ruling, the undersigned treats this case as a causation-in-

⁹ Section 11(b)(2) states that "[o]nly one petition may be filed with respect to each administration of a vaccine." Nevertheless, § 16(b) creates an exception to this limitation in cases where the Table is revised and "the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining such compensation."

fact case subject to the standard set forth in *Althen v. Sec’y of Health and Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

In a causation-in-fact case, the burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen*, 418 F.3d at 1278; *Hines v. Sec’y of Health and Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The showing of “causation-in-fact” must satisfy the “preponderance of the evidence” standard, the same standard ordinarily used in tort litigation. § 13(a)(1)(A); see also *Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is “more probable than not” that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279.

The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was a legal cause by showing that the vaccine was at least a “substantial factor” in causing the condition. *Shyface v. Sec’y of Health and Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). If petitioner makes this showing, petitioner has established that the vaccine is a legal cause of the harm. *Id.*

In *Althen*, the Federal Circuit articulated a three-part test incorporating requirements established in other decisions for demonstrating causation. The *Althen* court explained this “causation-in-fact” standard as follows:

Concisely stated, *Althen*’s burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If *Althen* satisfies this burden, she is “entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine.

Althen, 418 F.3d at 1278 (citations omitted). In finding causation, a fact-finder may rely upon “circumstantial evidence,” which the court found to be consistent with the “system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.” *Id.* at 1280.

Petitioner may establish a prima facie case that her injury was caused by a covered vaccine by satisfying the *Althen* test. *Deribeaux v. Sec’y of Health and Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013). “Once a petitioner establishes her prima facie case by satisfying the *Althen* test, the burden then shifts to the respondent to show by a preponderance of the evidence that the injury is due to factors unrelated to the administration of the vaccine. *Id.*

In determining whether a petitioner alleging a SIRVA has met the *Althen* criteria, the undersigned considers the Qualifications and aids to interpretation (“QAI”) included

in the revised Table for SIRVA to be persuasive regarding the factors necessary to demonstrate a logical sequence of cause and effect in a SIRVA case, even if the petition was filed prior to the effective date of the Table modification.

Whether a petition alleging a SIRVA was filed before or after the effective date of the Table modification has no impact on the scientific or medical understanding of the injury or mechanism of injury. In either case, the same issues are relevant to assessing causation. The Table criteria and QAI are the very criteria that the Secretary of Health and Human Services has determined are relevant to causation in a SIRVA case. Thus, the SIRVA Table criteria and QAI provide a framework for assessing causation in SIRVA cases regardless of whether they are analyzed under the Table or the *Althen* factors.

Therefore, the undersigned determines that in a case involving a SIRVA, the Table criteria and QAI are relevant to an analysis of whether a vaccine caused a SIRVA, regardless of whether the petition was filed before or after the date when the modification adding SIRVA to the Table became effective. In a case filed after the Table modification took effect, the analysis involves a straightforward determination of whether the Table and QAI criteria are met. In a case filed before the Table modification became effective, the analysis is slightly different but nevertheless involves application of the Table and QAI criteria. In such a case, the undersigned determines that the proper analysis is to apply *Althen* to determine whether a petitioner has proved her injury was caused in fact by the vaccination in question, and to use the Table and QAI as instructive in determining whether petitioner has met that burden.

VI. Analysis of Causation

Below, the undersigned first analyzes the three *Althen* prongs to determine whether petitioner has established a prima facie case that a covered vaccine caused her SIRVA. Next, because respondent asserts that a factor unrelated to the administration of a covered vaccine caused petitioner's injury, the undersigned analyzes which party has the burden of proof with respect to the "factors unrelated" and whether that burden of proof has been met.

For the reasons set forth below, the undersigned finds that petitioner has established that the Tdap vaccine was a substantial factor in causing her SIRVA. Next, the undersigned finds that pursuant to the Federal Circuit's decision in *Walther*, the burden of proof with respect to "factors unrelated" to the administration of a covered vaccine is on respondent. Finally, the undersigned finds that respondent has not met his burden to demonstrate that an unrelated factor caused petitioner's injury. Thus, the undersigned finds that petitioner has shown entitlement to compensation.

a. Petitioner's Prima Facie Case

Petitioner may establish a prima facie case that her injury was caused by a covered vaccine by satisfying the *Althen* test. *Deribeaux v. Sec'y of Health and Human Servs.*,

717 F.3d 1363, 1367 (Fed. Cir. 2013). “Once a petitioner establishes her prima facie case by satisfying the *Althen* test, the burden then shifts to the respondent to show by a preponderance of the evidence that the injury is due to factors unrelated to the administration of the vaccine.” *Id.* Therefore, the first step is to analyze whether petitioner has established the *Althen* prongs. For the reasons set forth below, the undersigned finds that she has.

i. *Althen* Prong One

Under *Althen* Prong One, there must be preponderant evidence of a medical theory causally connecting petitioner’s vaccination to her injury. In satisfaction of *Althen* Prong One, the undersigned takes judicial notice of the fact that respondent has added SIRVA to the Vaccine Injury Table for the influenza vaccine. See National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (*citing* Atanasoff et al., Court Ex. I); see also *Doe 21 v. Sec’y of Health and Human Servs.*, 88 Fed. Cl. 178 (July 30, 2009), *rev’d on other grounds*, 527 Fed. Appx. 875 (Fed. Cir. 2013) (holding that recognition of a link between vaccine and injury on the Vaccine Injury Table supports petitioner’s burden under *Althen* Prong One).

In adding SIRVA to the Table, the Secretary of Health and Human Services determined that, for vaccines listing SIRVA as a Table injury,¹⁰ there is a sufficient causal connection between the administration of such vaccines and SIRVA to warrant adding SIRVA to the Table. In other words, the Secretary has determined that intramuscular administration of certain vaccines can cause SIRVA.

Further, the literature and medical records filed in this case provide preponderant evidence of a medical causal theory. Atanasoff and Bodor set forth a proposed mechanism of injury, “the unintentional injection of antigenic material into synovial tissues resulting in an immune-mediated inflammatory reaction.” Atanasoff, Court Exhibit I at 1-3 (*citing* Bodor, Court Exhibit II). This occurs when the vaccine is “injected into the subdeltoid bursa . . . causing a robust local inflammatory and immune response” which leads to “bursitis, tendinitis, and inflammation of the shoulder capsule.” *Id.* at 2.

Moreover, two of petitioner’s physicians opined that petitioner had a left shoulder injury due to the October 19, 2015 vaccines administered in her left deltoid. On February 2, 2016, Dr. Nicholas Leroy of the Center for Progressive Health examined petitioner due to left shoulder pain following tetanus and shingles vaccines in her left deltoid in October. Pet. Ex. 2 at 3-4. Dr. Leroy assessed petitioner as having left “rot. [rotator] cuff syndrome 2° [secondary] to Oct 2015 vaccine shots [in left] deltoid.” *Id.* at 3.

¹⁰ The undersigned notes that the shingles vaccine is not listed in the Table and thus SIRVA is not a Table injury for the shingles vaccine, while SIRVA is a Table injury for Tdap. However, the undersigned does not view this difference as dispositive.

In addition, after examining petitioner and ruling out a back lipoma as a cause of petitioner's left shoulder condition, Dr. Ellis Nam assessed her with "Left shoulder pain, s/p [status post] tetanus/shingles injection on 10/2015." Pet. Ex. 24 at 3. Dr. Nam described petitioner's left shoulder condition as one that "she developed as a result of the tetanus/shingles shot in her left shoulder on October, 2015." Pet. Ex. 24 at 2.

Thus, petitioner has met *Althen* Prong One.

ii. *Althen* Prong Two

Under *Althen* Prong Two, petitioner must demonstrate a logical sequence of cause and effect showing that the vaccination was the reason for the injury. The undersigned determines that the SIRVA QAI criteria set forth a logical sequence of cause and effect and that by establishing that the QAI criteria are met, a petitioner may establish that *Althen* Prong Two has been met.

The criteria under the QAI for SIRVA are as follows:

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

82 Fed. Reg. 6303 (Qualifications and Aids to Interpretation for SIRVA).

In light of the factual history described above, the undersigned finds that all four of the criteria listed in the QAI for SIRVA are satisfied by preponderant evidence in this case.

1. No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection

Upon the undersigned's review, nothing in petitioner's prior medical history suggests any relevant history of pain, inflammation or dysfunction of petitioner's left shoulder.

2. Pain occurs within the specified time-frame

The question of when petitioner's shoulder pain first manifested is one of the bases for respondent's recommendation against compensation in this case. In his Rule 4(c) Report, respondent argued that the records did not establish that the onset of pain occurred within 48 hours of vaccination. Respondent's Rule 4(c) Report at 7 n.2. At the hearing and in the subsequent October 31, 2018 fact ruling, however, the undersigned resolved this factual dispute. The undersigned found that the onset of petitioner's injury occurred within 48 hours. This finding is supported by several pieces of evidence.

On February 18, 2016, Dr. Perrott documented "injections in left deltoid since October" and "since then" pain in the left shoulder region. Pet. Ex. 14 at 3. On December 22, 2015, Dr. Noriega documented that petitioner reported "left arm pain after two shots," Pet. Ex. 3 at 42. Dr. Townsend Scott also documented left shoulder pain that began after receiving two immunizations in the left arm. Pet. Ex. 3 at 326. The Center for Progressive Health documented that petitioner had "left shoulder pain following tetanus and shingles shots in left deltoid" in October. Pet. Ex. 2 at 3-4.

At the hearing, petitioner testified that she experienced immediate soreness following vaccination. Tr. 11. She testified that she repeatedly called the clinic to report the pain and was told to give it some time to go away. Tr. 11-12. She testified that on the day after vaccination she had limited movement in her arm and was still in pain. Tr. 14.

The undersigned finds that the preponderance of the evidence establishes that the onset of petitioner's pain was within 48 hours after vaccination.

3. Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered

The undersigned finds no evidence that petitioner's pain and reduced range of motion extended beyond her left shoulder. Petitioner consistently reported pain in her left shoulder. While a physician theorized that a lipoma on her back could be related, another physician opined that the back lipoma was unrelated to petitioner's shoulder pain. Moreover, petitioner testified that the lipoma has been on her back for 15 years and during that time has remained asymptomatic. The undersigned finds that the preponderance of the evidence establishes that petitioner's pain and reduced range of motion were limited to the shoulder in which the intramuscular vaccine was administered.

4. No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or

**clinical evidence of radiculopathy, brachial neuritis,
mononeuropathies, or any other neuropathy)**

The undersigned also finds no evidence of any condition or abnormality that would otherwise explain her symptoms. As noted above, the preponderance of the evidence establishes that petitioner's back lipoma does not explain petitioner's symptoms.

5. Additional considerations

Moreover, separate and apart from the specific requirements of the QAI, as noted above, there are additional considerations that weigh in favor of finding that petitioner has satisfied the second prong of *Althen*.

First, two of petitioner's treating physicians opined that petitioner's shoulder condition was vaccine-caused.¹¹ See, e.g. Pet. Ex. 2 at 3; Pet. Ex. 24 at 1. "[T]reating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show [s] that the vaccination was the reason for the injury.'" *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) (quoting *Althen*, 418 F.3d at 1280).

Second, the Federal Circuit's adoption of the Restatement (Second) of Torts and analysis in *Shyface* supports a finding that the Tdap vaccine was a substantial factor in causing petitioner's injury and thus the second *Althen* prong has been established.

In *Shyface*, the Federal Circuit adopted the Restatement (Second) of Torts and ruled that "an action is the 'legal cause' of harm if that action is a 'substantial factor' in bringing about the harm, and [the] harm would not have occurred but for the action." *Shyface*, 165 F.3d at 1352. In that case, petitioner's expert testified that an infant's death was caused by a high fever, which resulted from a combination of administration of a covered vaccine and an infection. *Shyface*, 165 F.3d at 1345-46. However, petitioner's expert could not determine which of these two factors was more responsible. *Id.* Thus, the special master ruled against the petitioners, finding that "[p]etitioners evidence of a vaccine-related cause stands *possibly in equipoise*, but no better." *Id.* at 1347 (quoting special master's decision) (emphasis added).

The Federal Circuit determined that evidence that the combination of the factors caused the death was sufficient to establish entitlement to compensation for a vaccine injury even if the vaccine was not the predominant cause, as long as it was a substantial factor. In determining whether it was a substantial factor, the Federal Circuit looked to the Restatement (Second) of Torts § 432(2), which states:

If two forces are actively operating, one because of the actor's negligence, the other not because of any misconduct on his part, *and each of itself is sufficient to bring about harm*

¹¹ While a treating physician also considered petitioner's back lipoma as a possible cause, Dr. Nam opined that the lipoma had no effect on petitioner's shoulder condition, Pet. Ex. 24, and the undersigned has already ruled that the lipoma did not cause petitioner's shoulder symptoms.

to another, the actor's negligence may be found to be a substantial factor in bringing it about.

Restatement (Second) of Torts § 432(2) (*quoted in Shyface*, 165 F.3d at 1352) (emphasis added).

Applying the Restatement § 432(2) here, respondent agrees that based on the facts in this case “it is impossible to attribute causation to one vaccine or the other.” Respondent’s December 7, 2018 Brief at *2-3 (ECF No. 67). In addition, the covered vaccine, Tdap, itself was sufficient to bring about harm. Thus, under these circumstances, the undersigned finds that the Tdap vaccine was a substantial factor in causing petitioner’s injury.

Thus, for all of the above reasons, the undersigned finds that petitioner has satisfied *Althen* Prong Two.

iii. *Althen* Prong Three

Under *Althen* Prong Three, there must be a proximate temporal relationship between vaccination and injury. In this case, both parties agree that the relevant medically accepted timeframe for onset of a SIRVA injury is within 48 hours of vaccination. As noted above, the undersigned found that the preponderance of the evidence supports a finding that the onset of petitioner’s SIRVA occurred within 48 hours of vaccination. Thus, petitioner has satisfied *Althen* Prong Three.

Because petitioner has satisfied all three *Althen* prongs and thus established a prima facie case, the burden then shifts to respondent to prove, by a preponderance of the evidence, that petitioner’s injury was caused by factors unrelated to the administration of the Tdap vaccine.

b. Factors Unrelated to Vaccination

In determining entitlement to compensation, Vaccine Act § 13(a)(1) provides:

Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole

- (A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title; and
- (B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to *factors unrelated to the administration of the vaccine described in the petition*.

Vaccine Act § 13(a)(1) (emphasis added).

Respondent asserts that two factors unrelated to the covered Tdap vaccination may have contributed to petitioner's injury. First, respondent asserts that petitioner's back lipoma may have contributed to her injury. As noted above, the undersigned has previously found that the preponderance of the evidence does not support this contention. This finding is supported by Dr. Nam's opinion that the lipoma was unrelated to petitioner's shoulder condition as well as petitioner's testimony, which the undersigned found credible.

Second, respondent asserts that on the date of vaccination, petitioner received two vaccines in her injured arm, a Tdap vaccine and a shingles vaccine. As determined above, by establishing the *Althen* factors are met, petitioner has established a prima facie case that the Tdap vaccine caused her SIRVA. For the purpose of fully addressing respondent's arguments, the undersigned analyzes this issue as a "factor unrelated to the administration of the vaccine" as well.

With limited exceptions related to polio that are not applicable here, to be entitled to compensation a petition must assert an illness or injury caused by a vaccine set forth in the Vaccine Injury Table, 42 C.F.R. §100.3. Vaccine Act § 11(c)(1). The Tdap vaccine is listed in the Table, while the shingles vaccine is not. See, e.g., *Duke v. Sec'y of Health and Human Servs.*, No. 15-473V, 2015 WL 4124547, at *2 (Fed. Cl. Spec. Mstr. June 12, 2015) ("The shingles vaccine is not listed on the Table and is therefore not covered by the Program" and noting the dismissal of previous petitions seeking compensation for injuries from the shingles vaccine). Respondent argues that petitioner has not established that the covered Tdap vaccine, rather than the non-covered shingles vaccine, caused her injury.

The undersigned previously made a fact finding that petitioner received both the Tdap and shingles vaccinations in her injured left arm. In her petition, petitioner listed all three vaccines received on October 19, 2015. Petition, filed Nov. 4, 2016, at ¶ 3 (ECF No. 1). However, in her second summary judgment motion, petitioner asserts entitlement to compensation based on the tetanus, or Tdap, vaccine. Petitioner's Second MSJ, filed Dec. 4, 2018, at 5 (ECF No. 66-1). In addition, the shingles vaccine is not a covered vaccine and petitioner asserts that the flu vaccine was administered into her right arm. Thus, the undersigned analyzes petitioner's claim as asserting entitlement to compensation based on the Tdap vaccine, which is listed in the Table. Above, the undersigned determined that petitioner had shown by a preponderance of the evidence that the Tdap vaccine caused her SIRVA and thus made the showing required under § 13(a)(1)(A) to establish a prima facie case.

Respondent asserts that petitioner testified that the vaccines were administered almost at the same time and that she felt tingling only after both were administered. Respondent's December 7, 2018 Brief at *2-3 (ECF No. 67). Thus, respondent asserts that "at best, the evidence is in equipoise with respect to the Tdap and shingles vaccines as the cause of petitioner's SIRVA." *Id.* at *3. Respondent argues that it is petitioner's burden to demonstrate that the Tdap vaccine was more likely to cause the

injury than the shingles vaccine and that because she cannot meet the burden, her claim must fail.

As discussed above, the undersigned determines that petitioner has met her burden to demonstrate that the Tdap vaccine was a legal cause of her SIRVA and thus has established a prima facie case.

Citing the Federal Circuit's decision in *Walther v. Sec'y of Health and Human Servs.*, 485 F.3d 1146 (Fed. Cir. 2007), petitioner asserts that under § 13(a)(1)(B), it is respondent's burden to prove that the injury petitioner asserts is vaccine-related was actually caused by a factor unrelated to the vaccination. In other words, petitioner asserts that it is respondent's burden to prove that the non-covered shingles vaccine caused the injury and that, unless he is able to do so, petitioner should prevail.

Walther is strikingly similar in that it also involves the question whether petitioner's injury was caused by a covered or non-covered vaccine. In *Walther*, the petitioner received four vaccines – tetanus-diphtheria (“Td”), yellow fever, and meningitis on July 31, 1997, and rabies on August 6, 1997. Of these four vaccines, only the Td vaccine was included in the Vaccine Injury Table. On August 7 and 8 she began experiencing trembling, weakness, and fatigue. She was ultimately diagnosed with post-vaccinal acute disseminated encephalomyelitis (“ADEM”). Petitioner's expert testified that it was more likely than not that her ADEM was caused by the Td vaccine and that, for reasons specific to each vaccine, the other vaccines she received were unlikely to have caused her illness. The government primarily argued that petitioner did not suffer from ADEM, but also contended that even if she suffered from ADEM, it was not caused by the Td vaccine.

The special master in *Walther* dismissed the petition, finding that Walther had not carried her burden to prove that her illness was caused by the Td vaccine, in part because she had not presented proof eliminating other potential causes for her injury. *Walther*, 485 F.3d at 1147.¹² The petitioner unsuccessfully sought review in the Court of Federal Claims. On appeal at the Federal Circuit, petitioner argued that the special master “applied an incorrect standard requiring her to eliminate other potential causes in order to establish a prima facie case of causation.” *Id.* at 1148. The Federal Circuit ruled that while petitioner may use evidence eliminating other potential causes to help carry the burden on causation, petitioner does not bear the burden of eliminating alternative independent potential causes. *Id.* at 1150-52. The court ruled that once petitioner has established a prima facie case, “the government bears the burden of establishing alternative causation by a preponderance of the evidence.” *Id.* at 1151.

The Federal Circuit noted that § 13(a)(1)(A) by its terms places the burden of proof on petitioner, while § 13(a)(1)(B) is silent with respect to burden of proof. *Walther*,

¹² The special master's decision in *Walther* was issued on July 29, 2005, the same day that the Federal Circuit issued its decision in *Althen*. The special master's *Walther* decision thus had applied a different causation standard than that set forth in *Althen*.

485 F.3d at 1150-51. The court stated that a “plain reading of the statutory text [of subsection (B)] more naturally places the burden on the government to establish that there is an alternative cause by a preponderance of the evidence.” *Id.* at 1150. The court reasoned that assigning the burden of proof under subsection B to plaintiff “would essentially write § 300aa-13(a)(1)(B) out of the statute.” *Id.*

The *Walther* court then looked to the Restatement (Second) of Torts, explaining that for purposes of causation a petitioner is treated as the equivalent of a tort plaintiff and the government as the equivalent of a tort defendant. The court noted that the Restatement (Second) of Torts § 433B(3) provided that in cases involving multiple independent potential causes, where harm has been caused by only one of them but there is uncertainty as to which one, “the burden is upon each such actor [tort defendant, or respondent in this case] to prove that he has not caused the harm.” *Walther*, 485 F.3d at 1151 (*quoting* Restatement (Second) of Torts § 433B(3) (1965)).

Applying this to the Vaccine Act, the court stated that “the petitioner generally has the burden on causation, but when there are multiple independent potential causes, the government has the burden to prove that the covered vaccine did not cause the harm.” *Id.* The court determined that “in both Table and off-Table [causation-in-fact, or *Althen*, cases] cases the government bears the burden of establishing alternative causation by a preponderance of the evidence once the petitioner has established a prima facie case.”¹³ *Id.*

Thus, in a case similar to this case, in that both involve the question of causation when a petitioner received multiple vaccines close in time, the Federal Circuit has addressed the very question at issue in this case and determined that the burden of proof with respect to alternative causes is on respondent.

In another case, the Federal Circuit cited *Walther* and stated that “[o]nce the petitioner has established a prima facie case for entitlement to compensation and thus met her burden to prove causation-in-fact, the burden shifts to the government to prove ‘[by] a preponderance of the evidence that [petitioner’s injury] is due to factors unrelated to the administration of the vaccine described in the petition So long as the

¹³ This rationale has been followed by Special Masters in other cases. See, e.g., *Heinzelman v. Sec’y of Health and Human Servs.*, No. 2007-01V, 2008 WL 5479123, at *17 (Fed. Cl. Spec. Mstr. Dec. 11, 2008) (concluding that petitioner’s “burden of proving ‘a logical sequence of cause and effect showing that the vaccination was the reason for the injury’ does not include the obligation to negate possible alternative causes” for her injury), *mot. for rev. denied*, 98 Fed. Cl. 808 (2011), *aff’d on other grounds*, 681 F.3d 1374 (Fed. Cir. 2012); *Al-Uffi v. Sec’y of Health and Human Servs.*, No. 2013-956V, 2017 WL 1713113, at *19 (Fed. Cl. Spec. Mstr. Feb. 22, 2017) (“Because I find that Petitioner has established her *prima facie* case by a preponderance of the evidence, the burden now shifts to Respondent to prove by a preponderance of the evidence an alternative, unrelated cause” for petitioner’s condition) (*citing Heinzelman*); *Deribeaux v. Sec’y of Health and Human Servs.*, No. 2005-306V, 2011 WL 6935504, at *33 (Fed. Cl. Spec. Mstr. Dec. 9, 2011) (assigning to respondent burden of proving that a factor unrelated to the vaccination caused the injury pursuant to § 13(a)(1)(B)), *mot. for rev. denied*, 105 Fed. Cl. 583 (2012), *aff’d*, 717 F.3d 1363 (Fed. Cir. 2013).

petitioner has satisfied all three prongs of the *Althen* test, she bears no burden to rule out possible alternative causes.” *de Bazan v. Sec’y of Health and Human Servs.*, 539 F. 3d 1347, 1352 (Fed. Cir. 2008). “Once causation is established, the petitioner is entitled to compensation unless the government can show by a preponderance of the evidence that the injury is due to factors unrelated to the vaccine, i.e., an alternative cause.” *Porter v. Sec’y of Health and Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011).

Pursuant to the reasoning set forth in *Walther*, the tort defendant, or respondent here, has the burden of proving that the non-covered vaccine, rather than the covered vaccine, caused petitioner’s injury. Respondent has offered no evidence, other than the fact that petitioner received a non-covered vaccine, to meet this burden.

Respondent asserts that the evidence as to which vaccine – Tdap or shingles – caused petitioner’s SIRVA is, at best, in equipoise. There is evidence showing that each vaccine was administered, but no evidence showing that either was more likely than the other to have caused petitioner’s SIRVA. However, the analysis is not either/or, as respondent suggests. Instead, the first inquiry is whether petitioner has established a prima facie case that the Tdap caused her injury; the undersigned has found that she has. The next inquiry is whether respondent has established by a preponderance of the evidence that a factor unrelated to the Tdap caused petitioner’s injury; the undersigned finds that he has not.

Respondent argues that a more recent Federal Circuit case, *Stone v. Sec’y of Health and Human Servs.*, 676 F.3d 1373, 1380 (Fed. Cir. 2012), “has limited the approach articulated in *Walther*, which presumably allows the special masters to ignore relevant evidence in the record when determining whether petitioners have met their burden of proving vaccine-causation by a preponderance of the evidence.” Respondent’s December 7, 2018 Brief at *2 (ECF No. 67).

The undersigned disagrees with respondent’s characterization of *Walther*. *Walther* does not permit a special master to ignore evidence. Rather, *Walther* addressed the issue of burden of proof on alternative causes.

With respect to *Stone*, the court in that case agreed that with “factors unrelated” evidence, “a special master *may not require the petitioner to shoulder the burden of eliminating all possible alternative causes in order to establish a prima facie case.*” *Stone*, 676 F.3d at 1380 (emphasis added). Nevertheless, in *Stone*, the Federal Circuit also stated that prior decisions support “the commonsense proposition that evidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.” *Id.* at 1379-80. The court further stated that “in some cases a sensible assessment of causation cannot be made while ignoring the elephant in the room – the presence of compelling evidence of a different cause for the injury in question.” *Id.* at 1380.

The undersigned notes that in *Walther*, the alternative causes asserted by respondent were four non-covered vaccines that petitioner received close in time to the sole covered vaccine she received. Respondent's position was that each of the non-covered vaccines represented a biologically plausible explanation for her condition. In contrast, in *Stone*, the asserted alternative cause was a genetic mutation that respondent's expert, who the special master found persuasive, testified was the sole cause of petitioner's illness. Thus, one distinction between these cases is that *Walther* deals with a situation where, as in this case, respondent is raising the simple fact of a non-covered vaccination as an alternative cause, whereas in *Stone*, respondent also presented persuasive expert testimony as to a genetic etiology.

In a case where a petitioner has received multiple vaccines, some listed in the Table and some not listed in the Table, in the same arm or other site, and is injured, it is somewhat difficult to reconcile the approaches of *Walther* and *Stone*. In such cases, as in this case, there may be little or no proof as to which vaccine or vaccines caused the injury. In such circumstances, the determination as to who has the burden of proof with respect to alternative causation may be dispositive.

One cohesive reading of *Walther* and *Stone* is that *Walther* applies in a situation where respondent simply identifies a possible alternative cause with nothing more, whereas *Stone* is relevant in a case where respondent presents an alternative cause *and* evidence that the finder of fact finds persuasive enough to defeat petitioner's prima facie case. This reading was suggested in *Heinzelman v. Sec'y of Health and Human Servs.*, No. 07-01V, 2008 WL 5479123 (Fed. Cl. Spec. Mstr. Dec. 11, 2008), *mot. for rev. denied*, 98 Fed. Cl. 808 (2011), *aff'd on other grounds*, 681 F.3d 1374 (Fed. Cir. 2012) ("Assuming that the Federal Circuit actually created a distinction between situations in which the government challenged the persuasive value of petitioner's evidence on a particular prong and situations in which the government put forth a particular agent as the cause of petitioner's injury, then the distinction is important").

Applying this reading to the facts of this case, *Walther* would govern because respondent has offered no evidence at all, much less persuasive evidence, to demonstrate that the non-covered shingles vaccine is more likely the cause of petitioner's injury than the covered Tdap vaccine. The undersigned interprets *Walther* as supporting a ruling in favor of petitioner if petitioner establishes a prima facie case and respondent does not establish by preponderant evidence that the injury was caused by an unrelated factor.

Therefore, the undersigned determines that petitioner has established a prima facie case that her SIRVA was caused by her Tdap vaccination. The undersigned further finds that respondent has not met his burden of showing that the non-covered shingles vaccine, rather than the covered Tdap vaccine, caused petitioner's SIRVA. *See Suffolk Tech., LLC v. AOL Inc.*, 753 F.3d 1358, 1367 (Fed. Cir. 2014) (affirming grant of summary judgment and placing on non-moving party the burden of presenting

evidence to undermine moving party's showing that there are no genuine issues of material fact).

Respondent argues that "it would be error for the Chief Special Master to ignore the fact that petitioner received an uncovered shingles vaccine in the same arm, and at the same time, as the covered Tdap vaccine when deciding whether petitioner has shown that the Tdap vaccine is the more likely cause of her SIRVA" (ECF No. 67 at *5). Respondent is mistaken.

First, the undersigned need not decide that the Tdap vaccine is the more likely cause of petitioner's SIRVA. The undersigned finds that petitioner has established a prima facie case that a covered vaccine, Tdap, caused her SIRVA. Pursuant to *Walther*, once petitioner has established a prima facie case, the burden shifts to respondent to demonstrate that an unrelated factor caused the injury, and respondent has offered no proof to meet this burden.

Second, the undersigned has not ignored that petitioner received a non-covered shingles vaccine in the same arm as she received her Tdap vaccine. The undersigned made this fact finding both at the end of the fact hearing and in a subsequent written fact ruling. However, respondent has the burden to prove that the shingles vaccine rather than the Tdap vaccine caused petitioner's SIRVA, and respondent has not offered any proof beyond mere administration of a non-covered vaccine and thus has not met his burden.

Respondent asserts in a footnote that petitioner initially attributed her injury to the shingles vaccine. Respondent's Response to October 31, 2018 Scheduling Order, filed Dec. 7, 2018, at *3 n.3 (ECF No. 67). Petitioner's medical records indicate in some notes that her pain began after a shingles vaccination and in other records that it began after receiving shingles and tetanus, or Tdap, vaccines, or simply after two immunizations, in her left arm. These statements are not inconsistent with each other and would not support a finding that petitioner attributed her injury solely to the shingles vaccine. Petitioner testified that she mentioned all three vaccines that she received to her medical providers. The undersigned found petitioner to be a credible witness and finds that the medical records are not inconsistent with petitioner's testimony.

In this case, whether analyzed as a Table case or as a causation-in-fact case, petitioner has established a prime facie case that a covered vaccine, Tdap, caused her SIRVA. Respondent has not established that a factor unrelated to the Tdap vaccine, either a back lipoma or a shingles vaccine, caused petitioner's injury. The issue of causation in this case is a close one. Keeping in mind that "close calls regarding causation are resolved in favor of injured claimants," *Althen*, 418 F.3d at 1280, the undersigned determines that petitioner is entitled to compensation.

VII. Conclusion

Thus, for all the foregoing reasons, **the undersigned finds that petitioner is entitled to compensation.** Accordingly, the undersigned **GRANTS** petitioner's motion for summary judgment (ECF No. 66) and rules that petitioner is entitled to compensation.

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey
Chief Special Master